EXHIBIT 17

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE MISSOURI DEPARTMENT OF SOCIAL SERVICES

JUNE GIBBS BROWN
Inspector General

JANUARY 1997
A-06-95-00067

SUMMARY

At the request of the Health Care Financing Administration (HCFA), the Office of Inspector General (OIG) conducted a nationwide review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. Since most States reimburse pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP), the objective of our review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs.

To accomplish our objective, we selected a random sample of 11 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a statewide managed care program for Medicaid. Missouri was one of the sample States, as well as California, Delaware, District of Columbia, Florida, Maryland, Montana, Nebraska, New Jersey, North Carolina, and Virginia.

Additionally, we selected a sample of Medicaid pharmacy providers from each State and obtained invoices of their drug purchases. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our overall estimates. We believed such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inflated our percentages.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between AWP and invoice price for each category.

In Missouri, we obtained pricing information from 37 pharmacies. Specifically, we obtained 2,675 invoice prices for brand name drugs, and 1,311 invoice prices for generic drugs. For Missouri, the overall estimate of the extent that AWP exceeded invoice prices was 18.5 percent for brand name drugs and 46.4 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. The estimates combine the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and exclude the results obtained from non-traditional pharmacies.

We are recommending that the Missouri Department of Social Services (State Agency) consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs. We will share the information with HCFA from all 11 States in a consolidation report for their use in evaluating the overall Medicaid drug program.

The Director of State Agency responded to our draft report in a letter dated, October 22, 1996. The Director stated the report would be of great assistance in their endeavor to optimize access to, and the quality of, health care services. The Director was appreciative of being included in the planning of this review. The full text of the Director's comments are included in Appendix 4.

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INTRODUCTION

At the request of HCFA, OIG, Office of Audit Services (OAS) conducted a review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the Missouri Department of Social Services (State Agency). The objective of our review was to develop an estimate of the difference between the actual acquisition costs of drugs and AWP. This review was conducted as a part of a nationwide review of pharmacy acquisition costs. Missouri was 1 of 11 States randomly selected as part of the nationwide review.

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by HCFA. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less some percentage. The AWP is the price assigned to the drug by its manufacturer and is listed in either the ***Red Book, Medispan*** or the ***Blue Book***--publications universally used in the pharmaceutical industry. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, HCFA issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In November 1990, the Omnibus Budget Reconciliation Act of 1990 was passed which placed a 4-year moratorium on changes to States' reimbursement policies. The moratorium expired on December 31, 1994 and HCFA requested that we, once again, determine the difference between AWP and actual pharmacy acquisition cost.

The State Agency reported drug expenditures of $241.8 million in Calendar Year (CY) 1994.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between AWP and the actual invoice prices of both brand name and generic prescription drugs to Medicaid pharmacy providers. Our objective did not require that we identify or review any internal control systems.

Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead. We also did not take into consideration the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations. We plan to evaluate the effect of the Federal upper limit amounts on generic drug reimbursements in a subsequent review.

We obtained a listing of all Medicaid pharmacy providers from the State Agency. The State Agency was responsible for classifying each pharmacy as chain, independent or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a December 31, 1992 listing of metropolitan areas and their components. We selected a stratified random sample of 60 pharmacies with 12 pharmacies selected from each of 5 strata--urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and would inflate our estimate.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1994. We identified the sources of supply as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. Each pharmacy was assigned a month from January through September in order to provide a cross-section of this 9-month time period. However, we permitted one pharmacy to provide invoices from December as invoices were not available from the earlier period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that the invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We attempted to obtain NDCs in those instances. We used the 1994 ***Red Book,*** a nationally recognized reference for drug product and pricing information, as a reference for drug product and pricing information, as a reference to obtain NDCs or identify over-the-counter items. One prominent wholesaler, whose invoices contained that wholesaler's item number rather than NDCs, provided us with a listing that converted their item number to an NDC. If we were unable to identify the NDC for a drug, we eliminated the drug. This was a common occurrence for generic drugs where there was no indication on the invoice as to the manufacturer of the drug.

We obtained a listing from HCFA that indicated whether a drug is a brand name or generic drug. We used that listing to classify each drug on the invoices as brand or generic. If a drug was not on the HCFA listing, we used the ***Red Book*** to determine whether the drug was brand or generic. Additionally, we obtained drug expenditure information from HCFA-64 Reports.

The State of Missouri provided us with a pricing file for the purpose of obtaining the AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file we eliminated that drug.

An initial meeting was held in Richmond, Virginia on August 30 - 31, 1994, with Medicaid pharmacy representatives from the sample States. At this meeting, we presented a methodology for performing the review and the methodology was refined with input from the State representatives. At a follow-up meeting held in Richmond, Virginia, on September 27 - 28, 1995, we presented the results of our review with the sample States.

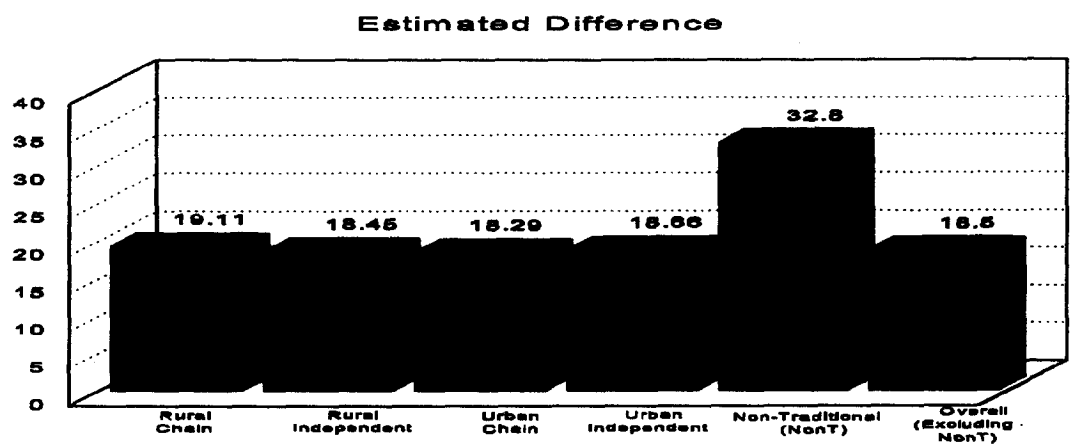
We used OAS statistical computer software to calculate all estimates as well as to generate all random numbers. We did not independently verify any information obtained from third party sources. Our review was conducted by our Little Rock, Arkansas OAS field office with assistance from our OAS field offices in Baton Rouge, Louisiana, and Austin, Texas from September 1994 to September 1995.

FINDINGS AND RECOMMENDATIONS

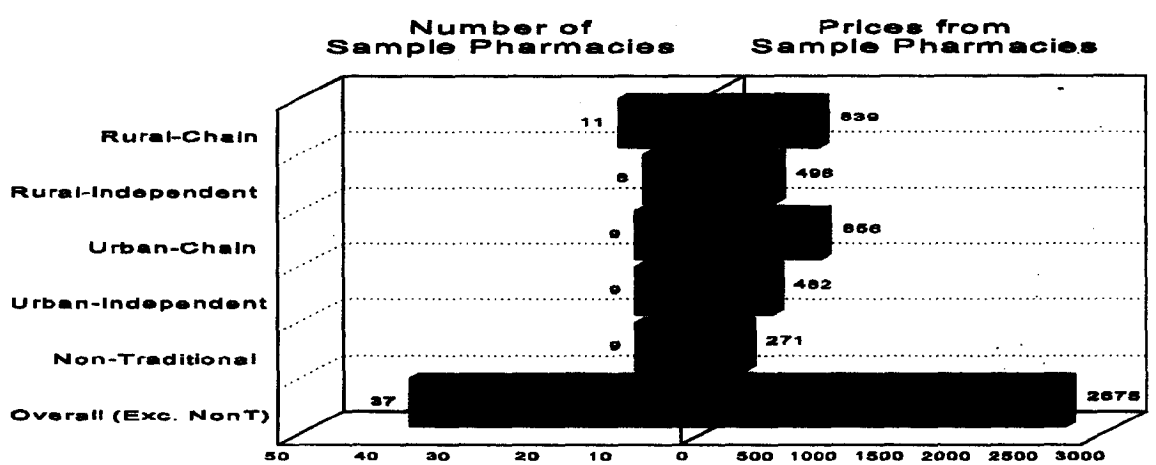
BRAND NAME DRUGS

We estimate that invoice prices for *brand name drugs* were discounted 18.5 percent below AWP. The estimate combined all pharmacy categories except for non-traditional pharmacies and was based on the comparison to AWP of 2,675 invoice prices received from 37 pharmacies. The standard deviation for this estimate was 0.27 percent (see Appendix 2).

The estimates that invoice prices for *brand name drugs* were discounted below AWP are summarized in the following chart:



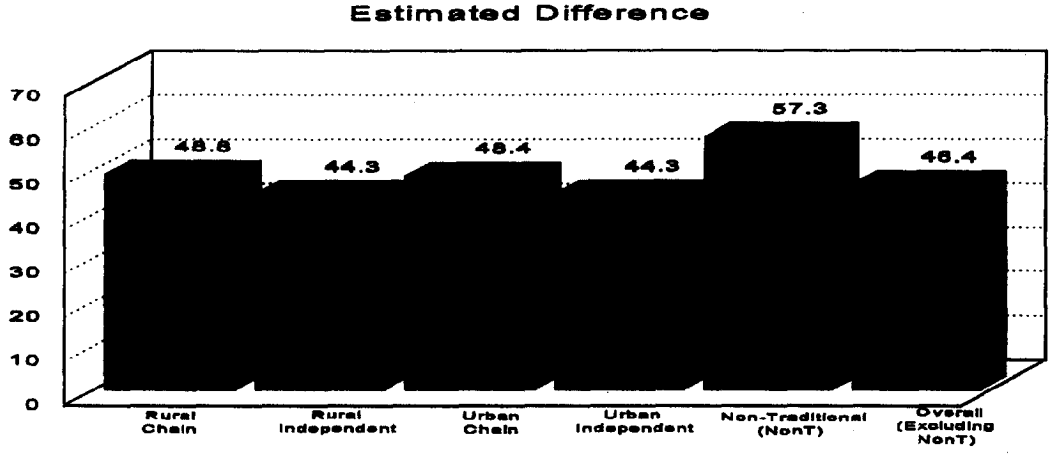
The following chart shows the number of pharmacies sampled and the number of prices reviewed by individual category for *brand name drugs*.



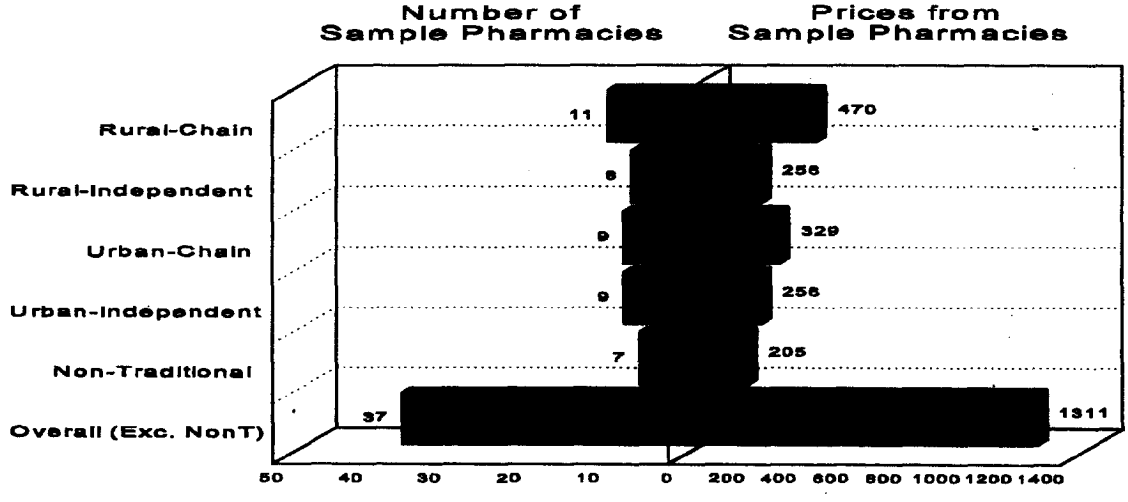
GENERIC DRUGS

We estimate that invoice prices for *generic drugs* were discounted 46.4 percent below AWP. Once again, the estimate combined all pharmacy categories except non-traditional pharmacies. The estimate was based on the comparison to AWP of 1,311 invoice prices received from 37 pharmacies. The standard deviation for this estimate was 1.30 percent (see Appendix 2).

The estimates that invoice prices for *generic drugs* were discounted below AWP are summarized by individual categories in the following chart:



The following chart shows the number of pharmacies sampled and the number of prices reviewed by individual category for the *generic drugs*.



CONCLUSIONS AND RECOMMENDATION

Based on our review, we have determined that there is a significant difference between AWP and pharmacy acquisition costs. The difference between AWP and pharmacy acquisition costs is significantly greater for generic drugs than for brand name drugs. In general, State representatives believed that the review supported current State practices to establish pharmacy reimbursement for ingredient cost at levels below AWP.

We recognize that acquisition cost is just one factor in pharmacy reimbursement policy and that any change to that policy should also consider the other factors discussed in the Scope section of our report. Additionally, the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations should be taken into consideration. However, a change in any of the factors affecting pharmacy reimbursement could have a significant impact on expenditures because of the size of the program ($241.8 million) in Missouri. We believe that the difference between AWP and pharmacy acquisition costs as determined by our review is significant enough to warrant consideration by the State in any evaluation of the drug program. Therefore, we recommend that the State Agency consider the results of this review in determining any future changes to pharmacy reimbursement for Medicaid drugs. 21291511

STATE AGENCY COMMENTS

The Director of State Agency responded to our draft report in a letter dated, October 22, 1996. The Director stated the report would be of great assistance in their endeavor to optimize access to, and the quality of, health care services. The Director was appreciative of being included in the planning of this review. The full text of the Director's comments are included in Appendix 4.

APPENDICES

SAMPLE DESCRIPTION

Sample Objectives:

Develop an estimate of the extent that invoice prices are discounted below Average Wholesale Prices (AWP) for Medicaid pharmacies in Missouri for brand name drugs and for generic drugs.

Population:

The sampling population was pharmacy providers participating in the Medicaid prescription drug program of the State Agency.

Sampling Frame:

The sampling frame was a listing of all pharmacy providers participating in the Medicaid prescription drug program.

Sample Design:

A sample of 12 pharmacies was randomly selected from each of 5 strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). Each pharmacy was assigned a month from 1994 for which to provide invoices. All pharmacies were initially assigned a month from January through September in a method designed to provide a cross-section of the 9-month period. However, one pharmacy was permitted to submit invoices from December as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Twelve pharmacies were selected from each stratum for a total of 60 pharmacies.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that did not provide information. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

Estimation Methodology:

We used OAS Statistical Software to project the percentage difference between AWP and actual invoice prices for each stratum, as well as an overall percentage difference. The overall percentage difference excluded the non-traditional pharmacies. The projections were done separately for brand name drugs and generics.

Other Evidence:

We obtained AWP from First DataBank.

APPENDIX 2

MISSOURI SAMPLE RESULTS
BRAND NAME AND GENERIC DRUGS

RURAL-CHAIN	139	11	839	19.11	1.19	18.54	19.68
RURAL-INDEPENDENT	227	8	498	18.45	0.70	18.05	18.85
URBAN-CHAIN	359	9	856	18.29	1.82	17.30	19.27
URBAN-INDEPENDENT	261	9	482	18.66	1.59	17.80	19.51
NON-TRADITIONAL	135	9	271	32.79	15.32	24.67	40.90
OVERALL (EXCL. NON-TRAD)	986	37	2,675	18.54	0.27	18.10	18.98
RURAL-CHAIN	139	11	470	48.75	5.64	46.06	51.43
RURAL-INDEPENDENT	227	8	256	44.34	6.93	40.38	48.30
URBAN-CHAIN	359	9	329	48.36	6.66	44.75	51.96
URBAN-INDEPENDENT	261	9	256	44.26	9.55	39.11	49.40
NON-TRADITIONAL	135	7	205	57.34	10.17	51.18	63.50
OVERALL (EXCL. NON-TRAD)	986	37	1,311	46.40	1.30	44.27	48.53

APPENDIX 3

NATIONWIDE SAMPLE RESULTS
BRAND NAME AND GENERIC DRUGS

RURAL-CHAIN	1,095	73	5,723	17.40	1.05	15.67	19.13
RURAL-INDEPENDENT	1,499	78	3,043	16.39	1.07	14.63	18.15
URBAN-CHAIN	8,194	73	7,198	18.45	0.52	17.60	19.31
URBAN-INDEPENDENT	6,242	91	3,009	18.71	0.90	17.22	20.19
NON-TRADITIONAL	2,026	66	1,762	27.52	2.28	23.76	31.27
OVERALL (EXCL. NON-TRAD)	17,030	315	18,973	18.30	0.66	17.21	19.38

RURAL-CHAIN	1,095	73	2,963	47.51	1.63	44.82	50.20
RURAL-INDEPENDENT	1,499	78	1,798	47.38	0.93	45.85	48.92
URBAN-CHAIN	8,194	72	2,634	37.61	2.82	32.97	42.26
URBAN-INDEPENDENT	6,242	91	1,680	46.72	2.44	42.70	50.73
NON-TRADITIONAL	2,026	59	1,262	57.70	1.98	54.43	60.96
OVERALL (EXCL. NON-TRAD)	17,030	314	9,075	42.45	0.90	40.97	43.93

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October 22, 1996

Ms. June Gibbs Brown
Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Review of Pharmacy Acquisition Costs (Draft) A-06-95-00067

Dear Ms. Brown:

The purpose of this letter is to provide comments on the draft report on the results of the above referenced OIG review of pharmacy acquisition costs for drugs reimbursed under the Missouri Medicaid pharmacy program. I apologize for our oversight in not responding earlier.

The Department of Social Services (DSS), through the University of Missouri Kansas City - School of Pharmacy, conducted a similar study, along with a cost to dispense study, in 1990-91. A copy of that report is enclosed for your review. The results of this study were similar, but indicated a wider range of discount rates experienced by Missouri pharmacies. The revision of Missouri Medicaid reimbursement methodology for pharmacy services, effective September 17, 1991, was based upon the results of this study. Reimbursement has remained at the revised level, AWP less 10.43% plus the standard professional fee of $4.09, since that date.

It was recognized in the 1990-91 study, as in your report, that ingredient cost is only one component to be considered in determining an appropriate pharmacy reimbursement level. Please note, that in September, 1991, the ingredient cost portion of the methodology was reduced to the amount reflected in the study; the standard professional dispensing fee was not raised to the recommended rate of $6.56 for independent pharmacies and $6.20 for chain pharmacies. The current standard dispensing fee of $4.09 remains below the established cost to dispense, as identified in the 1990-91 study ($5.69 for independent and $5.45 for chain pharmacies).

One of the goals of DSS is to optimize the access to and the quality of health care services to the department's clients, partners and stakeholders. Toward that end, we must identify and take into consideration as many essential variables as possible in order to develop reimbursement policies that are adequate for providers and fair to Missouri taxpayers. Your report will be of great assistance in that endeavor.

I would like to take this opportunity to express my appreciation that input from the states involved in this review, including Missouri, was requested prior to conducting the review. This team approach benefits both of our organizations.

Please feel free to contact Donna Checkett, Director, Division of Medical Services at 573-751-6922 if you have any further questions with regard to this matter.

Sincerely,

Gary J. Stangler
Director

GJS:ss

enclosure